Remarks

In response to the restriction requirement set forth in the Office Action mailed April 17, 2003, Applicants hereby provisionally elect Group I, claims 1-18, 79-125 covering a method of activating T cells and/or treatment and/or prophylaxis of a disease or condition comprising administration of GPI, derivative or equivalent or complex thereof.

In order to satisfy the species election requested by the examiner, Applicants elect a method of inducing an immune response, treatment, or prophylaxis of the disease condition, malaria. Further, as requested by the examiner, Applicants elect the species that entails using a GPI with the sequence:

EtN-P-[Mα2]Mα2Mα6Mα4Gα6Ino-Y,

as recited in claim 11.

Additionally, Applicants elect the upregulation of the Th2 response for examination, with traverse. The present invention relates to an antibody response which involves both Th1 and Th2 responses. Applicants are not claiming a specific cellular response involving a shift between the Th1 and Th2 responses. On this point, Applicants traverse the restriction requirement and request reconsideration.

Finally, in accordance with the examiner's request, a list of all claims readable on the elected claims are appended to the end of this response.

Applicants now await a first substantive action on the merits. Should there be any question regarding this application, the examiner is invited to contact the undersigned at the local exchange listed below.

Respectfully submitted,

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Date

Stephen A. Bent
Attorney for Applicants
Reg. No. 29,768

FOLEY & LARDNER
Customer Number: 22428
22428
22428
PATENT TRADEMARK OFFICE
Telephone: (202) 672-5300
Facsimile: (202) 672-5399

Pending Claims

1. (Original) A method of activating helper T cells said method comprising administering a T cell activating effective amount of GPI or derivative or equivalent thereof or a complex comprising GPI or derivative or eaquivalent thereof which GPI or GPI-complex is capable of interacting wutg CD1 on an immune cell to form an association with CD1 which association activates helper T cells.

2. (Original) The method according to claim 1 wherein said helper T cell is $CD4^+$ T cell.

3. (Original) The method according to claim 2 wherein said $CD4^+$ $NK1.1^+$ T cell.

4. (Previously presented) The method according to claim 1 wherein said complex comprises GPI and malarial CS protein or derivative or equivalent thereof.

5. (Previously presented) The method according to claim 1 wherein said complex comprises GPI and MSP-1 or derivative or equivalent thereof.

6. (Previously presented) The method according to claim 1 wherein said complex comprises GPI and MSP-2 or derivative or equivalent thereof.

7. (Previously presented) The method according to claim 1 wherein said complex comprises GPI and *Leishmanial* PSA-2 or derivative or equivalent thereof.

8. (Previously presented) The method according to claim 1 wherein said complex comprises GPI and GP63 or derivative or equivalent thereof.

9. (Previously presented) The method according to claim 1 wherein said GPI is a *Plasmodium* GPI.

10. (Original) The method according to claim 9 wherein said *Plasmodium* is *P. falciparum*.

11. (Previously presented) The method according to claim 1 wherein said GPI comprises a structure selected from:

EtN-P-[Mα2]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][G]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][X]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][EtN-P]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-Mα2Mα6Mα4G-Y

Mα2Mα6Mα4G-Y

EtN-P-Mα2Mα6M-Y

EtN-P-[Mα2][G]Mα2Mα6Mα4G-Y

EtN-P-[Mα2][X]Mα2Mα6Mα4G-Y

EtN-P-[Mα2][EtN-P]Mα2Mα6Mα4G-Y

Mα2[Mα2][G]Mα2Mα2Mα6Mα4G-Y

Mα2[Mα2][X]Mα2Mα6Mα4G-Y

Mα2[Mα2][EtN-P]Mα6Mα4G-Y

Mα6Mα4Gα6Ino-Y

Mα2Mα6Mα4Gα6Ino-Y

Mα2[Mα2]Mα6Mα4Gα6Ino-Y

Mα2[Mα2][G]Mα6Mα4Gα6Ino-Y

Mα2[Mα2][X]Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][G]Mα2Mα6M-Y

EtN-P-[Mα2][X]Mα2Mα6M-Y

EtN-P-[Mα2][EtN-P]Mα2Mα6M-Y

Mα2[Mα2][G]Mα2Mα6M-Y

Mα2[Mα2][X]Mα2Mα6M-Y

Mα2[Mα2][EtN-P]Mα6M-Y

Mα2Mα6M-Y

Mα6Mα4G-Y

EtN-P-[Mα2][G]Mα2M-Y

EtN-P-[Mα2][X]Mα2M-Y

EtN-P-[Mα2][EtN-P]Mα2M-Y

or derivatives or equivalents thereof wherein EtN is ethanolamine, P is phosphate, M is mannose, G is non-N-acetylated glucosamine, [G] is any non-N-acetylated hexosamine including glucosamine, or any other nitrous-acid labile substituent, Ino is inositol or inositol-phosphoglycerol, [X] is any other substituent, a represents a-linkages which may be substituted with β-linkages wherever required, numeric values represent positional linkages which may be substituted with any other positional linkages as required, and Y is any lipid or phospholipid.

12. (Original) The method according to claim 11 wherein said lipid is diacylglycerol, alkalacyglycerol, monoalkylglycerol, ceramide or sphingolipid.

13. (Original) The method according to claim 11 wherein said phospholipid is phosphatidylethanolamine, phosphatidylcholine or phosphatidylserine.

14. (Original) A method of activating helper T cells said method comprising administering a T cell activating effective amount of GPI or derivative or equivalent thereof or a

complex comprising GPI or derivative or equivalent thereof which GPI or GPI_complex is capable of interacting with CD1 on an immune cell to form an association with CD1 which association activates helper T cells wherein said activated T cells provide B cell help.

15. (Original) The method according to claim 14 wherein said helper T cell is a $CD4^+$ T cell.

16. (Original) The method according to claim 15 wherein said $CD4^+$ T cell is a $CD4^+$ $NK1.1^+$ T cell.

17. (Original) A method of activating helper T cells said method comprising administering a T cell activating effective amount of GPI or derivative or equivalent thereof or a complex comprising GPI or derivative or equivalent thereof which GPI or GPI-complex is capable of interacting with CD1 on an immune cell to form an association with CD1 which association activates helper T cells wherein said activated T cells induce or otherwise upregulate a TH1 type response.

18. (Original) A method of activating helper T cells said method comprising administering a T cell activating effective amount of GPI or derivative or equivalent thereof or a complex comprising GPI or derivative or equivalent thereof which GPI or GPI complex is capable of interacting with CD1 on an immune cell to form an association with CD1 which association activates helper T cells wherein said activated T cells induce or otherwise upregulate TH2 type response.

79. (Previously presented) The method according to claim 17 wherein said helper T cell is a $CD4^+$ T cell.

80. (Previously presented) The method according to claim 79 wherein said $CD4^+$ T cell is a $CD4^+$, NK1.1 T cell.

81. (Previously presented) A method of inducing, in a mammal, an immune response directed to GPI said method comprising administering to said mammal a T cell activating effective amount of GPI or derivative or equivalent thereof which GPI is capable of interacting with CD1 on an immune cell to form an association with CD1 which association activates helper T cells.

82. (Previously presented) The method according to claim 81 wherein said helper T cell is a $CD4^+$ cell.

83. (Previously presented) The method according to claim 82 wherein said $CD4^+$ T cell is a $CD4^+$ $NK1.1^+$ T cell.

84. (Previously presented) The method according to claim 81 wherein said GPI is *Plasmodium.*

85. (Previously presented) The method according to claim 84 wherein said *Plasmodium is P. falciparum.*

86. (Previously presented) The method according to claim 81 wherein said GPI comprises a structure selected from:

EtN-P-[Mα2]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][G]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][X]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][EtN-P]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-Mα2Mα6Mα4G-Y

Mα2Mα6Mα4G-Y

EtN-P-Mα2Mα6M-Y

EtN-P-[Mα2][G]Mα2Mα6Mα4G-Y

EtN-P-[Mα2][X]Mα2Mα6Mα4G-Y

EtN-P-[Mα2][EtN-P]Mα2Mα6Mα4G-Y

Mα2[Mα2][G]Mα2Mα6Mα4G-Y

Mα2[Mα2][X]Mα2Mα6Mα4G-Y

Mα2[Mα2][EtN-P]Mα6Mα4G-Y

Mα6Mα4Gα6Ino-Y

Mα2Mα6Mα4Gα6Ino-Y

Mα2[Mα2]Mα6Mα4Gα6Ino-Y

Mα2[Mα2][G]Mα6Mα4Gα6Ino-Y

Mα2[Mα2][X]Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][G]Mα2Mα6M-Y

EtN-P-[Mα2][X]Mα2Mα6M-Y

EtN-P-[Mα2][EtN-P]Mα2Mα6M-Y

Mα2[Mα2][G]Mα2Mα6M-Y

Mα2[Mα2][X]Mα2Mα6M-Y

Mα2[Mα2][EtN-P]Mα6M-Y

Mα2Mα6M-Y

Mα6Mα4G-Y

EtN-P-[Mα2][G]Mα2M-Y

EtN-P-[Mα2][X]Mα2M-Y

EtN-P-[Mα2][EtN-P]Mα2M-Y

or derivatives or equivalents thereof wherein EtN is ethanolamine, P is phosphate, M is mannose, G is non-N-acetylated glucosamine, [G] is any non-N-acetylated hexosamine including glucosamine, or any other nitrous-acid labile substituent, Ino is inositol or inositol-phosphoglycerol, [X] is any other substituent, α represents α-linkages which may be substituted with β-linkages wherever required, numeric values represent positional linkages which may be substituted with any other positional linkages as required, and Y is any lipid or phospholipid.

87. (Previously presented) The method according to claim 86 wherein said lipid is diacylglycerol, alkylacyglycerol, monoalkylglycerol, ceramide or sphingolipid.

88. (Previously presented) The method according to claim 86 wherein said phospholipid is phosphatidylethanolamine, phosphatidylcholine or phosphatidylserine.

89. (Previously presented) A method of inducing, in a mammal, an immune response directed to an antigen, said method comprising administering to said mammal a helper T cell activating effective amount of GPI or derivative or equivalent thereof complexed to said antigen, which GPI-antigen complex is capable of interacting with CD1 on an immune cell to form an association with CD1 which association activates helper T cells.

90. (Previously presented) The method according to claim 89 wherein said helper T cell is a $CD4^+$ T cell.

91. (Previously presented) The method according to claim 90 wherein said $CD4^+$ T cell is a $CD4^+$ $NK1.1^+$ T cell.

92. (Previously presented) The method according to claim 89 wherein said antigen is malarial CS protein or derivative or equivalent thereof.

93. (Previously presented) The method according to claim 89 wherein said antigen is MSP-1 or derivative or equivalent thereof.

94. (Previously presented) The method according to claim 89 wherein said antigen is MSP-2 or derivative or equivalent thereof.

95. (Previously presented) The method according to claim 89 wherein said antigen is *Leishmanial* PSA-2 or derivative or equivalent thereof.

96. (Previously presented) The method according to claim 89 wherein said antigen is GP63 or derivative or equivalent thereof.

97. (Previously presented) The method according to claim 89 wherein said GPI comprises a structure selected from:

EtN-P-[Mα2]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][G]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][X]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][EtN-P]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-Mα2Mα6Mα4G-Y

Mα2Mα6Mα4G-Y

EtN-P-Mα2Mα6M-Y

EtN-P-[Mα2][G]Mα2Mα6Mα4G-Y

EtN-P-[Mα2][X]Mα2Mα6Mα4G-Y

EtN-P-[Mα2][EtN-P]Mα2Mα6Mα4G-Y

Mα2[Mα2][G]Mα2Mα6Mα4G-Y

Mα2[Mα2][X]Mα2Mα6Mα4G-Y

Mα2[Mα2][EtN-P]Mα6Mα4G-Y

Mα6Mα4Gα6Ino-Y

Mα2Mα6Mα4Gα6Ino-Y

Mα2[Mα2]Mα6Mα4Gα6Ino-Y

Mα2[Mα2][G]Mα6Mα4Gα6Ino-Y

Mα2[Mα2][X]Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][G]Mα2Mα6M-Y

EtN-P-[Mα2][X]Mα2Mα6M-Y

EtN-P-[Mα2][EtN-P]Mα2Mα6M-Y

Mα2[Mα2][G]Mα2Mα6M-Y

Mα2[Mα2][X]Mα2Mα6M-Y

Mα2[Mα2][EtN-P]Mα6M-Y

Mα2Mα6M-Y

Mα6Mα4G-Y

EtN-P-[Mα2][G]Mα2M-Y

EtN-P-[Mα2][X]Mα2M-Y

EtN-P-[Mα2][EtN-P]Mα2M-Y

or derivatives or equivalents thereof wherein EtN is ethanolamine, P is phosphate, M is mannose, G is non-N-acetylated glucosamine, [G] is any non-N-acetylated hexosamine including glucosamine, or any other nitrous-acid labile substituent, Ino is inositol or inositol-phosphoglycerol, [X] is any other

substituent, α represents α-linkages which may be substituted with β-linkages wherever required, numeric values represent positional linkages which may be substituted with any other positional linkages as required, and Y is any lipid or phospholipid.

98. (Previously presented) The method according to claim 97 wherein said lipid is diacylglycerol, alkylacyglycerol, monoalkylglycerol, ceramide or sphingolipid.

99. (Previously presented) The method according to claim 97 wherein said phospholipid is phosphatidylethanolamine, phosphatidylcholine or phosphatidylserine.

100. (Previously presented) The method according to claim 81 wherein said activated helper T cell provides B cell help.

101. (Previously presented) The method according to claim 81 wherein said activated T cells induce or otherwise upregulate a TH1 type response.

102. (Previously presented) The method according to claim 81 wherein said activated T cells induce or otherwise upregulate a TH2 type response.

103. (Previously presented) A method for the treatment and/or prophylaxis of a mammalian disease condition comprising administering to said mammal an effective amount of GPI or derivative or equivalent thereof or a complex comprising said GPI or derivative or equivalent thereof which GPI or GPI-complex is capable of interacting with CD1 on an immune cell to form an association with the CD1 which association activates helper T cells.

104. (Previously presented) The method according to claim 103 wherein said helper T cell is a $CD4^+$ T cell.

105. (Previously presented) The method according to claim 104 wherein said $CD4^+$ T cell is a $CD4^+$ $NK1.1^+$ T cell.

106. (Previously presented) The method according to claim 103 wherein said activated T cell provides B cell help.

107. (Previously presented) The method according to claim 103 wherein said activated T cells induce or otherwise upregulate a TH1 type response.

108. (Previously presented) The method according to claim 103 wherein said activated T cells induce or otherwise upregulate a TH2 type response.

109. (Previously presented) A method for the treatment and/or prophylaxis of a mammalian disease condition characterized by microorganism infection, said method comprising administering to said mammal an effective amount of GPI or derivative or equivalent thereof or a complex comprising said GPI or derivative or equivalent thereof which GPI or GPI complex is

capable of interacting with CD1 on an immune cell to form an association with CD1 which association activates helper T cells.

110. (Previously presented) The method according to claim 109 wherein said microorganism infection is a parasitic infection.

111. (Previously presented) The method according to claim 110 wherein said complex comprises GPI and malarial CS protein or derivative or equivalent thereof.

112. (Previously presented) The method according to claim 110 wherein said complex comprises GPI and MSP-1 or derivative or equivalent thereof.

113. (Previously presented) The method according to claim 110 wherein said complex comprises GPI and MSP-2 or derivative or equivalent thereof.

114. (Previously presented) The method according to claim 110 wherein said complex comprises *Leishmanial* PSA-2 or derivative or equivalent thereof.

115. (Previously presented) The method according to claim 110 wherein said complex comprises GPI and GP63 or derivative or equivalent thereof.

116. (Previously presented) The method according to claim 109 wherein said GPI comprises a structure selected from:

EtN-P-[Mα2]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][G]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][X]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][EtN-P]Mα2Mα6Mα4Gα6Ino-Y

EtN-P-Mα2Mα6Mα4G-Y

Mαt2Mα6Mα4G-Y

EtN-P-Mα2Mα6M-Y

EtN-P-[Mα2][G]Mα2Mα6Mα4G-Y

EtN-P-[Mα2][X]Mα2Mα6Mα4G-Y

EtN-P-[Mα2][EtN-P]Mα2Mα6Mα4G-Y

Mα2[Mα2][G]Mα2Mα6Mα4G-Y

Mα2[Mα2][X]Mα2Mα6Mα4G-Y

Mα2[Mα21[EtN-P]Mα6Mα4G-Y

Mα6Mα4Gα6Ino-Y

Mα2Mα6Mα4Gα6Ino-Y

Mα2[Mα2]Mα6Mα4Gα6Ino-Y

Mα2[Mα2][G]Mα6Mα4Gα6Ino-Y

Mα2[Mα2][X]Mα6Mα4Gα6Ino-Y

EtN-P-[Mα2][G]Mα2Mα6M-Y

EtN-P-[Mα2][X]Mα2Mα6M-Y

EtN-P-[Mα2I[EtN-P]Mα2Mα6M-Y

Mα2[Mα2][G]Mα2Mα6M-Y

Mα2[Mα2][X]Mα2Mα6M-Y

Mα2[Mα2][EtN-P]Mα6M-Y

Mα2Mα6M-Y

Mα6Mα4G-Y

EtN-P-[Mα2][G]Mα2M-Y

EtN-P-[Mα2][X]Mα2M-Y

EtN-P-[Mα2][EtN-P]Mα2M-Y

or derivatives or equivalents thereof wherein EtN is ethanolamine, P is phosphate, M is mannose, G is non-N-acetylated glucosamine, [G] is any non-N-acetylated hexosamine including glucosamine, or any other nitrous-acid labile substituent, Ino is inositol or inositol-phosphoglycerol, [X]is any other substituent, α represents α-linkages which may be substituted with β-linkages wherever required, numeric values represent positional linkages which may be substituted with any other positional linkages as required, and Y is any lipid or phospholipid.

117. (Previously presented) The method according to claim 116 wherein said lipid is diacylglycerol, alkylacyglycerol, monoalkylglycerol, ceramide or sphingolipid.

118. (Previously presented) The method according to claim 116 wherein said phospholipid is phosphatidylethanolamine, phosphatidylcholine or phosphatidylserine.

119. (Previously presented) The method according to claim 109 wherein said parasitic infection is a *Plasmodium* infection.

120. (Previously presented) The method according to claim 119 wherein said *Plasinodium* is *P. falciparum.*

121. (Previously presented) The method according to claim 109 wherein said parasitic infection is a *Leishmania* infection.

122. (Previously presented) A method for the treatment and/or prophylaxis of a mammalian disease condition characterized by the insufficiency or absence of an appropriate TH1 response said method comprising administering to said mammal an effective amount of GPI or derivative or equivalent thereof or a complex comprising said GPI or derivative or equivalent thereof

which GPI or GPI complex is capable of interacting with CD1 on an immune cell to form an association with CD1 which association induces or otherwise upregulates a TH1 response.

123. (Previously presented) The method according to claim 122 wherein said disease condition is Leishmaniasis, a neoplastic condition or cancer.

124. (Previously presented) A method for the treatment and/or prophylaxis of a mammalian disease condition characterized by the insufficiency or absence of an appropriate TH2 response said method comprising administering to said mammal an effective amount of GPI or derivative or equivalent thereof or a complex comprising said GPI or derivative or equivalent thereof which GPI or GPI complex is capable of interacting with CD1 on an immune cell to form an association with CD1 which association induces or otherwise upregulates a TH2 response.

125. (Previously presented) The method according to claim 124 said disease condition is cerebral malaria, type I diabetes, autoimmune arthritis or systemic lupus erythromatosis.